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Attorney Docket No.: P-7945-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): PATERSON, David James Examiner: Hirianna, Kelaginamane
Serial No.: 10/534,888 Group Art Unit: 1632
Filed: September 27, 2005
Title: NITRIC OXIDE SYNTHASE GENE TRANSFER TO THE ATRIUM FOR VAGAL TONE INCREASE

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. _____ filed _____ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☒ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☒ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

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The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

- I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or
- II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

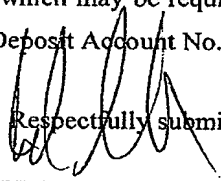
APPLICANTS: PATERSON, David James
SERIAL NO.: 10/534,888
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Page 3

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

- III) ☒ After the period in (I) and (II) but before the payment of the issue fee and,
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- b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
2. ☒ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,


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Attorney/Agent for Applicant(s)
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Dated: January 22, 2007

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<p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.</p> <p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(use as many sheets as necessary)</i></p>				Complete if Known	
				Application Number	10/534,888
				Filing Date	September 27, 2005
				First Named Inventor	PATERSON, David James
				Art Unit	
				Examiner Name	
				Attorney Docket Number	P-7945-US
Sheet	1	of	2		

[illegible][illegible]

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). * See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 601.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). * For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. * Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. * Applicant is to place a check mark here if English language translation is attached.

The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1460, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO		Complete if Known	
		Application Number	10/534,888
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	September 27, 2005
		First Named Inventor	PATERSON, David James
(use as many sheets as necessary)		Art Unit	
		Examiner Name	
Sheet	2	of	2
		Attorney Docket Number	P-7945-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C	ALEXANDER, et al (1999) "Gene transfer of endothelial nitric oxide synthase improves nitric oxide-dependent endothelial function in a hypertensive rat model" Cardiovascular Research 43(3):798-807.	<input type="checkbox"/>
	D	DANSON, et al (2003) "Impaired regulation of neuronal nitric oxide synthase during exercise abolishes training induced facilitation of cardiac vagal function in mice lacking one nNOS allele." Circulation Vol. 18 No. 17	<input type="checkbox"/>
	E	HEATON, et al (2003) "Cardiac nNOS gene transfer decreases beta-adrenergic hyper-responsiveness and enhances vagal function in spontaneously hypersensitive rats." Circulation Vol. 108 No. 17	<input type="checkbox"/>
	F	LI QIANHONG, et al (1999) "Powerful reduction in infarct size by in vivo adenovirus-mediated gene therapy with endothelial nitric oxide synthase" Circulation Vol. 100 No. 18	<input type="checkbox"/>
	G	MOHAN, et al (2002) "Enhanced NOS-1 expression with gene transfer promotes cardiac vagal gain of function." Circulation Vol. 106 No. 19	<input type="checkbox"/>
	H	MOHAN, et al (2002) "Neuronal nitric oxide synthase gene transfer promotes cardiac vagal gain of function" Circulation Research 91(12):1089-91.	<input type="checkbox"/>
	I	SAKAI, et al (2000) "Enhanced depressor response to nitric oxide synthase gene transfer into the nucleus of the solitary tract of spontaneously hypertensive rats" Journal of hypertension Vol. 18 No. 4	<input type="checkbox"/>
	J	Choate et al (2001) "Peripheral vagal control of heart rate is impaired in neuronal NOS knockout mice." Am J Physiol Heart Circ Physiol 281 pp H2310-H2317	<input type="checkbox"/>
	K	Li et al (2002) "Effect of in vivo gene transfer of nNOS in the PVN on renal nerve discharge in rats." Am J Physiol Heart Circ Physiol 282 pp H594-H601	<input type="checkbox"/>
	L	West et al (2001) "Nitric Oxide Synthase (nNOS) Gene Transfer Modifies Venous Bypass Graft Remodeling: Effects on Vascular Smooth Muscle Cell Differentiation and Superoxide Production." Circulation 104 pp 1526-1532	<input type="checkbox"/>
	M	Yu et al (2000) "Gene transfer of the neuronal NO synthase isoform to cirrhotic rat liver ameliorates portal hypertension." J Clin Invest 105 pp 741-748	<input type="checkbox"/>
	N	Danson & Paterson (2003) "Enhanced neuronal nitric oxide synthase expression is central to cardiac vagal phenotype in exercise-trained mice." J Physiol 546, pp 225-232	<input type="checkbox"/>

Examiner Signature	Date Considered
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